

**REMARKS/ARGUMENTS**

The Examiner's attention to the present application is noted with appreciation.

**Amendment to the Specification.** The first paragraph of the application ("Cross-Reference to Related Applications") is updated to reflect issuance of the parent. The second paragraph of the application ("Government Rights") is deleted; Applicant has determined that on the basis of the claims as amended the U.S. Government does not have rights in the invention.

**Amendment to the Claims.** Claim 8 is amended, to provide that the pharmaceutically acceptable carrier is an aqueous carrier, and to that the peptide is a free acid or pharmaceutically acceptable salt comprising the sequence Nle-cyclo(-Asp-His-D-Phe-Arg-Trp-Lys)-OH. Claim 9 is amended to specify that the peptide is cyclicized through the side chains of Asp and Lys without introduction of an additional molecular unit. Claim 10 is amended to provide that the peptide has an amino terminus acetylated amino group.

Claim 12 is amended to add "to stimulate a sexual response."

Claims 20-27 are canceled.

Claim 28 is added and claims "substantially pure" peptide. The method of synthesis (see Example 1) describes a purified peptide.

Claim 29 is added and claims "isolated" peptide. The method of synthesis (see Example 1) describes a purified peptide.

Claims 30-33 are added, and claim a pharmaceutical kit including the pharmaceutical composition disposed in a nasal administration device. The nasal administration device is described, *inter alia*, at Example 16.

Claim 34 is added and claims a "manufactured" peptide of a specific structure. The method of synthesis (see Example 1) describes a manufactured peptide.

**Claim Rejections - Statutory Basis Double Patenting.** Claim 11 is rejected under 35 U.S.C. § 101 as claiming the same invention as that of claim 7 of prior U.S. Patent No. 6,579,968. This ground of

rejection is respectfully traversed. Claim 8 is amended to provide a “pharmaceutically acceptable aqueous carrier.” It is submitted that this claim is no longer coextensive in scope with that of claim 7 of the '968 patent; the pharmaceutical composition of claim 7 of the '968 patent is not limited to an aqueous carrier.

**Claim Rejections - Obviousness Type Double Patenting.** Claims 8-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,579,968. A terminal disclaimer is submitted herewith.

**Claim Rejections - 35 U.S.C. § 112.** Claims 8-10, 20-22 and 24-27 are rejected under 35 U.S.C. § 112, first paragraph. This ground of rejection is respectfully traversed. Claims 20-27 are canceled, and the rejection is accordingly moot with respect to those claims. Claim 8 is amended, and as limited it is submitted that the specification is enabling. Use of a variety of amino terminus modifications is known in the art. Further, it is known in the art to, for example, employ derivatized amino acid residues, such one or more substituents on a ring core structure, such as one or more halogen substituents on a phenyl ring of a D-Phe residue.

**Claim Rejections - 35 U.S.C. § 112.** Claims 12-27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, on the asserted groups that the claims lack an essential step in the method of stimulating sexual response, which is “the outcome of method.” This ground of rejection is respectfully traversed. Claim 12 has been amended to address this ground of rejection, and claims 20-27 are canceled.

**Claim Rejection - 35 U.S.C. § 102.** Claims 8-10 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Hruby et al., or alternatively De Wied et al., or alternative Greven et al. This ground of rejection is respectfully traversed. Claims 8-10 are amended so as to render this rejection moot. None of the cited references teach a peptide comprising the sequence the sequence Nle-cyclo(-Asp-His-D-Phe-Arg-Trp-Lys)-OH, as claimed in claim 8 as amended.


In view of the above amendments and remarks, it is respectfully submitted that all grounds of rejection and objection have been avoided and/or traversed. It is believed that the case is now in condition for allowance and same is respectfully requested.

If any issues remain, or if the Examiner believes that prosecution of this application might be expedited by discussion of the issues, the Examiner is cordially invited to telephone the undersigned attorney for Applicant at the telephone number listed below.

Also being filed herewith is a Petition for Extension of Time to February 24, 2004, with the appropriate fee. Authorization is given to charge payment of any additional fees required, or credit any overpayment, to Deposit Acct. 13-4213. A duplicate of this paper is enclosed for accounting purposes.

Respectfully submitted,

By:



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